

REMARKS

This paper is in response to the Office Action mailed May 28, 2003. Reconsideration of the application is respectfully requested.

This application contains claims 1-13, 19, 20 and 21-32, of which claims 21-32 are new.

Claims 1-13 relate to a process for preparing a chewable or disintegrative tablet, comprising forming a tablet having a friability of less than about 2% from a mixture comprising a pharmaceutically active ingredient, an excipient in the form of a hydrate, and a water-swallowable excipient, and then applying sufficient energy to the tablet for a sufficient time to decrease the hardness of the tablet by at least about 20%.

Claims 19 and 20 relate to a tablet comprising: a) a pharmaceutically active ingredient, b) dextrose monohydrate, and c) crospovidone.

Finally, claims 21-32 relate a process for preparing a chewable or disintegrative tablet, comprising forming a tablet having a friability of less than about 2% from a mixture comprising a pharmaceutically active ingredient, an excipient in the form of a hydrate, and a water-swallowable excipient, and then applying sufficient heat to the tablet for a sufficient time to decrease the hardness of the tablet by at least about 20%.

The Examiner has withdrawn the previous indication of allowability, and rejected claims 1-13, 19 and 20 under 35 U.S.C. §112, first paragraph, as not enabled by the specification. The Examiner argues that applicants' have not provided enough details of the claimed process to enable one skilled in the art to practice it using energy sources other than heat. The Examiner suggests that the only energy sources identified are heat and microwaves, and that while a temperature generally in the range of ambient to 100° C is taught, no other description of appropriate energy is given.

First, in the interest of advancing prosecution, applicants have added claims 21-32 wherein the energy source is heat. Support for these claims is provided in the examples, as

well as original claim 2. Applicants submit that these claims are fully enabled by the specification, and should be allowed.

Second, it should be noted that original claims 19 and 20 are drawn to a tablet comprising: a) a pharmaceutically active ingredient, b) dextrose monohydrate, and c) croscopovidone. The pending rejection under §112 is therefore not applicable to these claims.

Third, claim 2 depends from claim 1 and recites that energy is provided in the form of heat. Accordingly, the rejection under §112 is also not applicable to claim 2, which is allowable.

Finally, applicants submit that the rejection of claims 1-13 for lack of enablement is also without merit. The disclosure is enabling for energy other than in the form of heat. The Examiner admits that the level of skill in the art is high. One skilled in this field would easily understand how to select an energy source and apply it, whether it is heat, microwaves, or otherwise. The specification on page 6 explains what is believed to happen when energy is applied to the tablet, and why this is advantageous:

application of energy to the tablet releases the water of hydration from the excipient in the form of a hydrate. The excipient in the form of a hydrate then becomes only partially hydrated, while the water-swellable excipient becomes hydrated or swollen, thereby softening the tablet. Softening is achieved without the need for an external source of water. The present tablet can therefore advantageously be made using simple direct compression methods.

The direct compression process enables the minimization or elimination of water-soluble, non-saccharide polymeric binders such as polyvinyl pyrrolidone, alginates, hydroxypropyl cellulose, hydroxypropylmethylcellulose, hydroxyethylcellulose, and the like, which can have an adverse effect on dissolution.

The Examples illustrate and prove this effect. The fact that the Examiner may be surprised by this phenomenon shows just how non-obvious and unexpected the claimed invention is.

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Contrary to the Examiner's position, applicants submit that the amount of experimentation required to select an energy source would not be undue, as the level of unpredictability here is not as great as suggested by the Examiner. Accordingly, withdrawal of the rejection under Section 112 is respectfully requested.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

By: 

Sharon E. Hayner  
Reg. No. 33,058

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-2242  
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